Electronic health records: International, structural and legal perspectives*

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Summary

The EHR is a database record that incorporates a patient's health care details from conception to death and which can be distributed over a number of sites or aggregated at a particular source. This article describes the function and concept of the EHR by relating it to other medical information technologies, other changes in health care delivery, and a holistic health information model. The article compares the progress that Europe, Australia, and the US have made in the journey towards EHR implementation and concludes by highlighting some of the costs, barriers and consequences associated with the transition to a comprehensive EHR system.

INTRODUCTION

As described by the Australian National Electronic Health Records Taskforce, the electronic health record (EHR) is "[a]n electronic longitudinal collection of personal health information usually based on the individual, entered or accepted by health care providers, which can be distributed over a number of sites or aggregated at a particular source".[1] Thus, the EHR is a database record that incorporates a patient's health care details from conception to death, although even that description is being rapidly outdated by our ability to associate genetic histories and predictions with an individual's record.

Appreciation of the importance of the EHR to the future of quality health care delivery has been partially obscured by the more visible electronic medical record (EMR). The EMR, which also attracts labels such as the electronic patient record (EPR) or electronic personal health record (PHR), is a more limited creature, defined as "[t]he record of the periodic care provided mainly by one institution … that [t]ypically … will relate to the health care provided to a patient by an acute hospital".[2] Periodic and fragmented, the EMR will be an important "front-end" component of the EHR architecture because it allows providers to convert their information "silos" into electronic format. In contrast, the EHR is the mechanism that unifies those silos and will accelerate the integration of longitudinal patient information into the next generation of health information technologies, including Computerised Physician Order Entry (CPOE) and Clinical Decision Support Systems (CDSS), and generally improve the quality of point-of-care decision-making.

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[1] National Electronic Health Records Taskforce, *A Health Information Network for Australia, Report to Health Ministers by the National Electronic Health Records Taskforce* (Commonwealth Department of Health and Aged Care, Canberra, 2000) p 21 (hereinafter Taskforce): http://www.health.gov.au/healthconnect/pdf_docs/ehr_rep.pdf.

[2] NHS Information Authority, *Information for Health – 2. Supporting Patient Care* at [2.10]: http://www.nhsia.nhs.uk/text/pages/info4health/2.asp. Viewed July 2004.

This article first describes the function and concept of the EHR by relating it to other information technologies that define the landscape of technologically mediated care, provides the EHR a broader context by relating it to other changes in health care delivery, and relates it to a more holistic health information model. Second, the article provides a brief description of the progress that major mature health systems have made in the journey towards EHR systems, noting differences in models and commenting on broader, distinguishing developmental trends. The article concludes by highlighting some of the costs, barriers and consequences associated with the transition to a comprehensive EHR system.

CONTEXT AND CONCEPT

Health care information technologies

Even more so than with their EMR subset, EHR technology models are dependent on and intimately interconnected with other records-related health care information technologies (IT) such as picture archiving and communication systems (PACS) and "store and forward" technologies that allow such imaging or other video data to be viewed remotely. In a parallel development, the inherent inefficiencies of health care delivery have given rise to technologies designed to streamline health care transactions, for example the United States Data Interchange (EDI) system which mandates an interoperable, standardised system for processing all data exchanges between health care entities.[3]

More importantly, EHR is the core technology promoted by the patient-safety movement. The publication of major national studies of medical error rates in the United States and Australia[4] has led to broad calls for amelioratory systems or process redesign of health care delivery[5] leading to the harnessing of technology to reduce error. A consensus has formed that the rapid, massive infusion of technology into health care is a key component in process-based reform.[6] Indeed, the Institute of Medicine (IOM) has urged "a renewed national commitment to building an information infrastructure to support health care delivery, consumer health, quality measurement and improvement, public accountability, clinical and health services research, and clinical education", leading to "the elimination of most handwritten clinical data by the end of the decade".[7]

This IT-led system reform is centred on several intersecting technologies that may be grouped as tracking, entry, decision-support and reporting:

- "Tracking" or identifying technologies such as barcodes and accompanying scanners positively identify drugs, dosages and patients.[8] Radio Frequency Identification (RFID) "track and trace" technologies may displace barcode technologies for identifying tasks and further allow positive tracking of drugs[9] and, potentially, patients.[10]
- "Entry" technologies are represented by computerised physician order entry (CPOE) systems that avoid medication errors caused by illegibility and other recording mistakes.[11]
- "Decision-support technologies" (CDSS)[12] are evolved order entry systems that have lost their passivity and reference drug interaction information, EHR data, or treatment models (such as

[3] See below text at 35.
[4] Wilson RM, Runciman WB, Gibberd RW, Harrison BT, Newby L and Hamilton JD, "The Quality in Australian Health Care Study" (1995) 163 MJA 458.
[5] See generally Leape LL, "Preventing Medical Accidents: Is 'Systems Analysis' the Answer?" (2001) 27 Am JL & Med 145 at 147; Reason J, "Human Error: Models and Management" (2000) 320 BMJ 768.
[6] Committee on Quality of Health Care in America, *Crossing the Quality Chasm: A New Health System for the 21st Century* (Institute of Medicine, 30 March 2001) p 15.
[7] Committee on Quality of Health Care in America, n 6, p 166 (Recommendation 9).
[8] See generally "Bar Code Label Requirement for Human Drug Products and Biological Products", 69 FR 9120 (26 February 2004).
[9] See *Combating Counterfeit Drugs, A Report of the Food and Drug Administration* (February 2004) at 1(e): http://www.fda.gov/oc/initiatives/counterfeit/report02_04.html#radiofrequency (noting adoption of RFID as the standard track and trace technology feasible by 2007). Viewed June 2004.
[10] See eg "New Research Project for RFID in Health-Care Industry", *InformationWeek*, 4 May 2004: http://www.informationweek.com/story/showArticle.jhtml?articleID=19502134 (discussing research project focusing on the use of RFID for tracking pharmaceutical products through the supply chain). Viewed June 2004.
[11] See generally "Cal Health Care Found, E-Prescribing" (2001): http://www.chcf.org/documents/hospitals/EPrescribing.pdf.

clinical practice guidelines), and which offer considerable advantages over simple CPOE systems.[13] Related are interactive devices such as appliances used for telecare[14] that collect and monitor data from remotely located patients and trigger further evaluation and treatment.

- "Reporting" systems provide for adverse event and medical error disclosure and reporting[15] and facilitate outcomes research.[16]

Finally, an array of privacy and security-enabling technologies has developed in step with the increasing computerisation of health care delivery. These include physical security systems, authentication technologies including biometrics, and various data integrity technologies such as firewalls and off-site storage services that protect against or minimise the effects of virus or hacker attacks.

Mature EHR implementations will leverage these various technologies. Crucially, EHR systems also will provide much-needed cohesion by, for example, providing patient-related data for input into decision-support systems, triggering individual error-reporting and feeding outcomes into population-based data systems.

Changes in delivery driving EHR implementation

The idealist might conclude that the world's health care delivery systems' commitment to technology has been driven by a shift in health care policy designed to improve and increase patient access to services.[17] Of course, many of the emerging technologies, such as Internet access to personal and educational health data provided by traditional and non-traditional "providers" and the adoption of home telecare appliances, will have that effect.[18] Particularly in the United States, however, the adoption of IT has been driven by business concerns, including the imperatives of reducing transaction costs and minimising expensive medical errors.

In seeking to explain the emergence of EHR systems in the United States, Tang and Hammond place particular emphasis on the formative role of managed care,[19] whereby fee-for-service plans have been replaced by lower-cost plans that emphasise wellness and preventive care and coordinate care through primary care physicians. In this managed care environment, the "gate-keeping" primary care physician requires access to both clinical and administrative data and decisional tools such as clinical pathways. Further, the cost structure of managed care has led to horizontal and vertical consolidation of providers into what are known as integrated delivery systems. The successful leveraging of these complex integrated systems is heavily dependent on information technologies. The (typically employer) payers for such systems have demanded performance "report cards", while system administrators use ever increasingly sophisticated utilisation review. Increasingly, these data are

[12] See generally Kaushal R and Bates DW, "Computerized Physician Order Entry (CPOE) with Clinical Decision Support Systems (CDSSs)" in *Making Health Care Safer: A Critical Analysis of Patient Safety Practices*, Prepared for Agency for Healthcare Research and Quality, Evidence Report/Technology Assessment, No 43, July 2001, Ch 6: http://www.ahrq.gov/clinic/ptsafety/pdf/ptsafety.pdf. Viewed June 2004.

[13] See eg Bobb A, Gleason K, Husch M, Feinglass J, Yarnold PR and Noskin GA, "The Epidemiology of Prescribing Errors: The Potential Impact of Computerized Prescriber Order Entry" (2004) 164 Arch Intern Med 785 (noting the desirability of matching CPOE systems to decision support and pharmacy systems to reduce medication errors). See Fernando B, Savelyich BSP, Avery AJ, Sheikh A, Bainbridge M, Horsfield P et al, "Prescribing Safety Features of General Practice Computer Systems: Evaluation Using Simulated Test Cases" (2004) 328 BMJ 1171.

[14] See generally Celler BG, Lovell NH and Chan DKY, "The Potential Impact of Home Telecare on Clinical Practice" (1999) 171 MJA 518: http://www.mja.com.au/public/issues/171_10_151199/celler/celler.html. Viewed June 2004.

[15] See eg Australian Council for Safety and Quality in Health Care, *Open Disclosure: A National Standard for Open Communication in Public and Private Hospitals Following an Adverse Event in Health Care* (July 2003): http://www.safetyandquality.org/articles/publications/OpenDisclosure_web.pdf.

[16] See generally Agency for Healthcare Research and Quality (AHRQ), *Outcomes & Effectiveness*: http://www.ahrq.gov/clinic/outcomix.htm. Viewed June 2004.

[17] See generally Terry NP, "A Medical Ghost in the E-Health Machine" (2004) 14 (1) *Health Matrix* 225.

[18] See generally Celler, Lovell and Chan, n 14.

[19] Tang PC and Hammond WE, "A Progress Report on Computer-based Patient Records in the United States" in Detmer DE, Steen EB and Dick RS (eds), *The Computer-based Patient Record: An Essential Technology for Health Care* (rev ed, IOM, USA 1997) pp 2-3.

provided to patients and regulators.[20] Such error and near-miss reporting systems are dependent upon data that are difficult to generate without sophisticated coding and nearly impossible to analyse without complex, comprehensive database systems.

Other aspects of changes in the business and concept of health care delivery also have had a detectible impact on the health care technology growth and the necessity for EHR data. For example, Tang and Hammond further identify the impact of another cost-controlling mechanism – the shift from inpatient to ambulatory care and how that shift places novel demands on patient data flow between geographically distinct providers.[21]

Of growing importance worldwide are other discernible changes in healthcare delivery and health priorities that similarly reinforce the necessity for comprehensive and easily accessible patient data. First, even without the distortions caused by the structural needs of managed care, it is clear that health policy has embraced the concept of "shared care". This phrase is used to denote two changes in the practical realities of the provider-patient relationship: first, patients should share responsibility with their provider for care; and second, patients are now likely to have relationships with multiple providers. For these restructured relationships to result in improved outcomes, patients must have access to health data generally and, more controversially, information in their record, while in multiple-provider scenarios there must be data transparency between the various providers involved in treatment or prescribing.

Data needs also are central to the increasing emphasis of health care delivery systems on population-based health with its emphasis on prevention and early treatment of illness. Population-based health care, in common with other emerging health care reforms, is increasingly data-driven and particularly reliant on outcomes assessment.[22] Western systems also are increasingly adopting disease surveillance programs integrated into their national bio-defence programs.[23]

The health information domain

A final context that needs to be provided for the development of EHR models is a more holistic model that the author has described elsewhere as the "health information domain".[24] Clearly, technology alters the way patient health data are acquired, stored, aggregated, processed, accessed and distributed. In the health information domain these processes illuminate inherent tensions between the key stakeholders and their needs:

- government access and security for public health and bio-defence;
- regulators with health quality agendas;
- health care institutions' access for quality assurance and marketing; and
- patient interests in confidentiality, privacy and anonymity.

Because of these tensions and the overall complexity of the health information domain, it is helpful to parse it by reference to some of its more important properties – properties that extend beyond the traditional, such as the confidentiality inherent in the physician-patient relationship, and into the modern realm of data protection, health quality and population-based health care.

Data are (or should be) protected courtesy of properties that feature substantive and process controls. The former are best described by the properties of:

- "confidentiality" (that controls disclosure);
- "privacy" (that controls collection); and

[20] See generally Landro L, "The Informed Patient: Consumers Need Health-Care Data", *Wall Street Journal*, 29 January 2004, p D3, available at 2004 WL-WSJ 56918499.
[21] Tang and Hammond, n 19, p 2.
[22] See eg United States Preventive Services Task Force (USPSTF): http://www.ahrq.gov/clinic/uspstmeth.htm. Viewed June 2004.
[23] See eg Centers for Disease Control and Prevention , *Bioterrorism and Public Health Preparedness*: http://www.cdc.gov/programs/bio.htm. Viewed June 2004.
[24] The "health information domain" and its properties are more fully described in Terry NP, "Privacy and the Health Information Domain: Properties, Models and Unintended Results" (2003) 10 Eur J Health L 223. For a similar model see Health*Connect Business Architecture Version 1.0, April 2003,* pp 30-31 (hereinafter Business Architecture): http://www.health.gov.au/healthconnect/pdf_docs/bav1.pdf. Viewed June 2004.

- "anonymity" (that empowers data subjects to refuse to supply data or to restrict identifiers).

Process controls are described by the properties of

- "security" (in essence, a confidentiality correlate that restricts access to data to those to whom they may be disclosed); and
- "integrity" (that features basic "checksum" validation and also protects against unauthorised modification).

The "access" property describes the various recognised claims to view and, in some cases, modify patient information. Justice and public health systems make the most persistent claims. However, most mature health information domains also recognise patients' rights of access and correction of their own data. Outcomes assessment and error-reporting mandates will substantially increase demands for access to individual and population-based health records from accreditation bodies and government regulators.

Three further properties of the health information domain require highlighting in the context of emerging EHR models: "unity," "quality" and "accountability." Information domains lose their value proposition when they are incomplete or their data are otherwise flawed. "Unity" refers to health information that is "longitudinal", consisting of records from various providers that are interlinked to provide a comprehensive view of a patient's health care encounters. A longitudinal approach provides the data necessary for technological models (such as CDSS systems) that analyse diagnoses and treatments and supports shared care from multiple providers. The "security" and "integrity" properties of the domain are fundamental to effective implementation of EHR models. As important, however, is "quality": the data must be current or timely and subject to quality auditing from extrinsic sources such as clinical practice guidelines. Finally, the "accountability" property denotes not only substantive responsibility by providers for the accuracy of the data they enter but also procedural identification of providers responsible for specific data.

EHR PROGRESS IN MATURE HEALTH SYSTEMS

The EHR will be the "central nervous system" of the health care system.[25] According to the IOM, its core functions will be:

1. longitudinal collection of electronic health information for and about persons;
2. electronic access to person- and population-level information by authorised users;
3. provision of knowledge and decision-support systems; and
4. support for efficient processes for health care delivery.[26]

Eventually, it will be against such a functional model that the progress of health care delivery systems towards EHR implementation must be measured. The limited progress of mature health care systems renders moot any current evaluation, although Australia, the United Kingdom, and the United States have all made recent significant progress and demonstrated a high level of commitment to the EHR ideal.

Europe

Van Bemmel et al report that "[c]omputer-based information systems are now abundant in a large percentage of European hospitals as well as in primary care settings".[27] They state that, by 1996, 50% of Dutch primary care physicians (general practitioners) had CPR systems, and suggest a similar number for the United Kingdom.[28] These systems (a few pilot studies aside), however, seem to be EMR information silos rather than true EHR systems because, as the same authors note, "[t]he data in CPRs are not begging to be used for electronic data exchange, research and shared care".[29]

[25] Ellwood PM, "Outcomes Management: A Technology of Patient Experience" (1988) 318 NEJM 1549 at 1550.
[26] Institute of Medicine, *Patient Safety: Achieving a New Standard for Care, Key Capabilities of an Electronic Health Record System* (Nov 2003) p 3, n 1.
[27] van Bemmel JH, van Ginneken AM and van der Lei J, "A Progress Report on Computer-based Patient Records in Europe" in Detmer, Steen and Dick, n 19, p 21.
[28] See n 27, p 23.
[29] See n 27, p 22.

A quite different conclusion is likely to be applied to the United Kingdom's radical National Programme for IT (NPfIT).[30] The NPfIT has four goals:

- electronic appointment booking;
- an electronic care records service;
- electronic transmission of prescriptions; and
- an IT infrastructure.[31]

The United Kingdom Government has committed to an investment of £2.3 billion over three years and three times that in the following seven years. The NPfIT has been somewhat rocked by changes in its leadership and disputes with a major contractor. However, the EHR component ("NHS Care Records Service") is reported to be on schedule.

Progress towards any longitudinal EHR that would link patient records across the European Union has been slow. In part, this is due to the limited legal authority that the European federal authorities have in the health care domain.[32] One concrete plan is to introduce electronic health cards for European Union citizens by 2008; these would facilitate treatment for citizens notwithstanding where in the Union they seek treatment. Questions remain, however, as to which technologies to adopt (for example, optical or magnetic data storage on the cards) and whether the data stored on or authenticated by the cards would be solely transactional or whether they would reference longitudinal patient health information.[33]

The European Union has a robust history in EHR research, having funded the "Good European Health Record" (GEHR) project from 1992 to 1995.[34] The GEHR has morphed into the *open*EHR Community[35] and has been an influential force in the development of Australia's Health*Connect* and clinical messaging formats such as the Health Level 7 (HL7) standards.[36] Implementation of a pan-European health information infrastructure,[37] however, remains somewhat aspirational with the federal authorities stating only that "Member States should develop health information networks between points of care (hospitals, laboratories and homes) with broadband connectivity where relevant".[38]

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[30] See generally http://www.dh.gov.uk/PolicyAndGuidance/InformationTechnology/NationalITProgramme/fs/en. Viewed June 2004. See also "England Plans Major Revamp of Health Care", *Wall Street Journal*, 3 December 2003, p B1, 2003 WL-WSJ 68129874 (in 2002 United States health care computer spending increased 9.3% to US$23.6 billion); Igbokwe O, "The National Programme for IT (NPfIT): An Intro", 2003 http://papers.biohealthmatics.com/papers/it_strategy/100011.aspx. Viewed July 2004.

[31] See http://www.dh.gov.uk/PolicyAndGuidance/InformationTechnology/fs/en. Viewed July 2004.

[32] See eg *Federal Republic of Germany v European Parliament and Council* (Case C-376/98) (Annulling Directive 98/43/EC of the European Parliament and of the Council of 6 July 1998 on the approximation of the laws, regulations and administrative provisions of the Member States relating to the advertising and sponsorship of tobacco products).

[33] Ministers welcomed the initiative on the European Health Insurance Card announced at the Barcelona Council and endorsed by the Seville Council as part of the eEurope 2005 Action Plan. Ministers encouraged the Commission to explore further initiatives in developing European Electronic Health Cards also taking into account the recent Communication from the Commission (COM (2003)73) on the European Health Insurance Card: Ministerial Declaration, Brussels, 22 May 2003: http://europa.eu.int/information_society/eeurope/ehealth/conference/2003/doc/min_dec_22_may_03.pdf. Viewed June 2004. See generally *e-Health, The Information Society, Setting the Targets*: http://europa.eu.int/information_society/eeurope/2005/all_about/ehealth/text_en.htm. Viewed June 2004.

[34] See http://www.chime.ucl.ac.uk/work-areas/ehrs/GEHR/index.htm. Viewed June 2004.

[35] See http://www.openehr.org/. Viewed June 2004.

[36] See http://www.hl7.org/. Viewed June 2004.

[37] Ministers noted that the full exploitation of the benefits of eHealth technologies requires continued commitment to the development and use of a robust, secure and interoperable infrastructure, as well as to wide availability and use of broadband communications to maximise the efficiency of eHealth systems and applications. Commission of the European Communities, *eEurope 2005: An Information Society for All*, Communication from the Commission to the Council, the European Parliament, the Economic and Social Committee and the Committee of the Regions, Brussels, 28 May 2002, COM(2002) 263 final, at 13: http://europa.eu.int/information_society/eeurope/2002/news_library/documents/eeurope2005/eeurope2005_en.pdf. Viewed July 2004.

[38] Id.

Australia

Health*Connect*,[39] Australia's proposed national health information network,[40] has the highest profile amongst EHR models in mature health care systems. Its development has been open, truly consultative, and the network has already completed two years of pilot tests. The originally distinct Medi*Connect*,[41] a longitudinal medication record project, has now been subsumed into the Health*Connect* model.[42] The Health*Connect* architects estimate that a fully operational system will save A$300 million per year by, for example, reducing errors and duplication of tests.[43]

The Australian EHR concept differs somewhat from the longitudinal model being developed in the United States. The basic Health*Connect* model has been described as follows:

> [A] person's health-related information would be collected in a standard, electronic format at the point of care (such as at a hospital or a GP's clinic). This information would take the form of health summaries, rather than all the notes that a health care provider may choose to keep about a consultation.
>
> With the consumer's consent, these summaries would then be able to be retrieved at any time they were needed and exchanged via a secure network between those particular health care providers authorised by the consumer to access this information.[44]

Thus Health*Connect* is built around some features that distinguish it from other developing models. First, in contrast to the horizontal interoperable model being developed in the United States, it is a vertical or top-down system. Second, it is not a "pull" model in the sense of the centralised EHR system initiating a data request from an individual provider. Rather, doctors, with the consent of their patients, may selectively "push" data to the centralised record.[45]

Third, the Health*Connect* system will not be the recipient of full patient records, but only "event summaries", defined as "critical information considered to be useful to other health care providers involved in the future care of the consumer that will be automatically extracted from tagged data in existing records".[46] In part following from the "summary" model but primarily from the system's voluntary structure, Health*Connect* does not create a true longitudinal record; rather, patients will choose which elements may be extracted from their existing record(s) and pushed to the Health*Connect* record and, further, which elements of the centralised record may be used for what purposes or "views".[47] For example, patients might elect to include details of their psychotropic prescriptions in their event summaries to be viewed by all their prescribing doctors, but only consent to their psychiatrists' discharge order being viewed by other mental health professionals.

Compared to a typically understood and comprehensive longitudinal record, Health*Connect* event summaries could have the advantage of supplying future or parallel providers with more relevant

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[39] See http://www.healthconnect.gov.au. Viewed June 2004.

[40] Health*Connect* is a joint federal-State initiative but is primarily financed by the Federal Government and led by the Commonwealth Department of Health and Ageing. It had its genesis in the report of the National Electronic Health Records Taskforce: see n 1.

[41] See http://www.mediconnect.gov.au/. Viewed June 2004. See generally Business Architecture, n 24, pp 44-45.

[42] See Health*Connect Budget Fact Sheet*, May 2004, at 3: http://www.health.gov.au/healthconnect/pdf_docs/hcbfs1105.pdf. Viewed June 2004.

[43] Business Architecture, n 24, p 7.

[44] "*Health*Connect – An Introduction": http://www.healthconnect.gov.au/pdf_docs/fshci.pdf. Viewed June 2004. See also Business Architecture, n 24, p 19: "Event summaries (subsets of the complete information recorded by providers) are produced in standard formats for key health events such as home visits by a community nurse, general practice and specialist consultations and hospital inpatient stays. These summaries will then be forwarded to Health*Connect*. Providers, given the appropriate authority, and consumers will be able to draw on previously forwarded events summaries and view the information through a series of structured 'views', defined to make the information meaningful to the individual provider or consumer."

[45] Health*Connect* denies that it is either a "push" or "pull" system: "Generally Health*Connect* would not pull data from operational systems, rather that it would receive event summaries pushed from operational systems. Health*Connect* would not generally push data to operational systems, rather that it would send the views/reports in response to a request": Business Architecture, n 24, p 7.

[46] Business Architecture, n 24, p 20, para 4.3: Event summaries.

[47] Business Architecture, n 24, p 23, para 4.5: EHR views and reports.

patient data. The relevancy of medical data, however, tends to be a function of the receiving provider and the treatment he or she is to provide rather than the selectivity of the source provider or patient.

Autonomy (and politics) aside, the system's laudable dedication to voluntary participation is perhaps somewhat justified on the basis that patients are already selective about what they tell their doctors and strategic in the way they change providers, and so an opt-in process harnesses these desires rather than fights against them. Practical considerations, however, may well defeat that article of faith. For example, could a truly sustainable voluntary model survive in the face of clinical negligence verdicts against doctors who elect not to use Health*Connect*? Could successful comparative negligence defences be raised against patients who opted-out? Further, the proposed system is also intended to achieve the following "secondary" goals:

- creating a best-practice, evidence-based health system through generation of new knowledge and better education and professional development of health care providers, planners and policymakers;
- improving utilisation of health resources through implementation of better, more targeted health initiatives and better planning;
- improving access to services;
- improving safety of health care services through activities such as enabling rapid response to treatment and device failures;
- supporting research and education; and
- detecting outbreaks of disease.[48]

Operationally, achieving these secondary objectives will require far more comprehensive data sets, albeit in some cases data that have been de-identified.

As with the nascent United States system discussed below, Health*Connect* is addressing complex technical specifications that include messaging and communication, medical terminologies and classification schemes.[49] Health*Connect* is being rigorously tested and continually reassessed by its architects and government paymasters. It may eventually morph into a longitudinal system or, at the other extreme, end up being more like the controversial "Australia Card".[50]

United States

Research on purchasing trends for physician offices in the United States for 2002-2004 suggests a decline in amounts spent on practice management systems (US$949 million to US$856 million) and a parallel increase in spending on EMR systems (US$574 million to US$1,023 million).[51] Estimates (in 2003) of EMR penetration vary, with the IOM suggesting 5 to 10% of Physician Offices[52] (and a similar penetration, 9% for CPOE systems[53]), but the California HealthCare Foundation found 20 to 25%.[54]

At first sight, hospitals show a slightly more robust penetration of prescribing and records technologies. According to the IOM, CPOE adoption is at 33%[55] while 20% of hospitals have electronic medical records systems.[56] Another estimate, however, suggests that by 2004 only 300 of the nation's 4,900 non-governmental hospitals had adopted the technology[57] and, further, that only 40

[48] Business Architecture, n 24, p 8.
[49] Business Architecture, n 24, p 34.
[50] See generally Greenleaf G, "The Australia Card: Towards A National Surveillance System" (1987) http://austlii.edu.au/itlaw/articles/GGozcard.html. Viewed June 2004.
[51] *EMRs for Small Physician Groups, Forrester Report* (December 2003).
[52] IOM, n 26, p 3.
[53] IOM, n 26, p 3.
[54] Brailer DJ and Terasawa EL, *Use and Adoption of Computer-based Patient Records* (California HealthCare Foundation, October 2003).
[55] IOM, n 26.
[56] IOM, n 26, p 3.
[57] Freudenheim M, "Many Hospitals Resist Computerized Patient Care", *New York Times*, 6 April 2004, p C1.

fully met the standards for such systems set by the Leapfrog Group.[58] The IOM has been duly critical of the rate of technology adoption by United States hospitals:

> In most of the nation's hospitals, orders for medications, laboratory tests and other services are still written on paper, and many hospitals lack even the capability to deliver laboratory and other results in an automated fashion. The situation is no different in most small practice settings, where there has been little, if any, migration to electronic records.[59]

Of course the United States health care system serves a very large population and is comprised of State, federal, private and non-profit business models that complicate implementation of an EHR. There are signs, however, that some of the largest private providers are increasing the pace of EHR adoption. For example, Kaiser Permanente, the largest non-profit HMO in the United States, with some 8.4 million members in nine States and 12,000 doctors, has recently adopted a three-year, US$1.8 billion EHR/EMR program.[60]

In the public sector the Department of Veterans Affairs (VA) has established itself as the poster child for publicly funded and *provided* health care that is committed to process reform and technologically mediated delivery of services.[61] However, even the VA has found itself the subject of intense criticism over issues such as a lack of interoperability with Department of Defense (DOD) systems.[62]

Much of the impetus for the implementation of IT in health care delivery to reduce costs and errors has come from non-profit organisations whose corporate sponsors are motivated by both genuine altruism and a heavy dose of frustration at the continued rise in health care costs. Thus, the influential Leapfrog Group[63] has chosen specific patient safety initiatives such as CPOE adoption and standards,[64] evidence-based hospital referral (a program designed to match patients with high-risk conditions to hospitals associated with better outcomes for those conditions[65]), and increasing the use of "intensivists" to staff ICUs.[66] More dominant in the EHR movement has been the "Connecting for Health"[67] initiative funded by the Markle Foundation.[68] One of the key components of that initiative is a "Working Group on Policies for Coordination across the EHR and the PHR",[69] which is concentrating on data standards[70] with a view to "[a]ccelerating the rate of adoption of national clinical data standards in order to facilitate true interoperability".[71] Overlapping with this initiative is the work of the EHR Collaborative,[72] which consists of the major professional stakeholders such as the American Medical Association and the Healthcare Information and Management Systems Society[73] and which has coordinated responses and feedback on the HL7 data standards.

Although there is a general interlocking of EHR developments, the foundational initiatives are being promoted by the non-governmental Institute of Medicine[74] and the National Committee on

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[58] See n 57.
[59] IOM, n 26, p 3, App E.
[60] "Big HMO Plans to Put Medical Records Online", *Wall Street Journal*, 4 February 2003 at D4, 2003 WL-WSJ 3958350.
[61] See eg National Center for Patient Safety (NCPS), *Creating a Culture of Safety*: http://www.patientsafety.gov/vision.html. Viewed June 2004.
[62] See generally *Computer-based Patient Records: Subcommittee Questions Concerning VA and DOD Efforts to Achieve a Two-Way Exchange of Health Data*. GAO-04-691R, 2004. http://www.gao.gov/cgi-bin/getrpt?GAO-04-691R. Viewed July 2004.
[63] See generally http://www.leapfroggroup.org/FactSheets/LF_FactSheet.pdf. Viewed June 2004.
[64] See http://www.leapfroggroup.org/FactSheets/CPOE_FactSheet.pdf. Viewed June 2004.
[65] See http://www.leapfroggroup.org/FactSheets/EHR_FactSheet.PDF. Viewed June 2004.
[66] See http://www.leapfroggroup.org/FactSheets/ICU_FactSheet.pdf. Viewed June 2004.
[67] See http://www.connectingforhealth.org/. Viewed June 2004.
[68] See http://www.markle.org/. Viewed June 2004.
[69] See http://www.connectingforhealth.org/workinggroups/pol_coordinationwg.html. Viewed June 2004.
[70] Data Standards Working Group, *Report and Recommendations* (5 June 2003): http://www.connectingforhealth.org/resources/dswg_report_6.5.03.pdf. Viewed June 2004.
[71] Data Standards Working Group, n 70 at 1.
[72] See http://www.ehrcollaborative.org. Viewed June 2004.
[73] See generally http://www.ehrcollaborative.org/index.htm. Viewed June 2004.
[74] The IOM is a member of the National Academies of Science which received its charter from the United States Congress as an independent advisory body: http://www.iom.edu/faq.asp?id=2959. Viewed June 2004.

Vital and Health Statistics (NCVHS), the latter being a statutory body that advises the Federal Government's Secretary of Health and Human Services.[75] The work of these two bodies has identified the properties of the United States patient safety data model and its core EHR architecture.[76] Unlike the United Kingdom and Australian proposals, the United States system is not conceived as a vertical top-down, comprehensive EHR solution; rather IOM and NCVHS are concentrating on creating standards for the horizontal interoperability of the diverse public and private records systems in the United States. While the NCVHS and IOM agree on a public-private partnership to achieve these goals, IOM has been somewhat more explicit in its calls for federal funding[77] and legislative or regulatory initiatives.[78]

Both IOM and NCVHS see the task ahead as involving two core components: first, building a national health information infrastructure;[79] and second, establishing data interoperability and comparability for patient safety-related data.[80] The second task is the more complex, technically. It involves creating standards for messaging, identifiers and data elements. Some of the identifier and messaging standards[81] adopted by the United States Federal Government, pursuant to the *Health Insurance Portability and Accountability Act 1996* (US),[82] to create a national health care transactional system (an electronic data interchange or EDI system) are transferable to an EHR system. In the interim, these messaging formats for clinical data (as they will be used in EHRs) have been further developed by organisations such as HL7,[83] DICOM[84] and the National Council for Prescription Drug Programs.[85]

Considerably more challenging, however, is specifying the standards required for EHRs and EHR data to achieve what NCVHS refers to as semantic interoperability and comparability, such that "the meaning of data is consistent when shared among different parties".[86] Here, both NCVHS[87] and IOM[88] have recommended the adoption of core EHR terminologies dealing with, for example, disease (ICD-9[89]), medical procedures and services (CPT-4[90]), and drug names or doses (for example, RxNorm[91]). Considerable development is also under way to standardise event taxonomy (such as

[75] 42 USC §242k(k).
[76] National Committee on Vital and Health Statistics, *Report on Uniform Data Standards for Patient Medical Record Information* (6 July 2000) (hereinafter Uniform Data Standards): http://www.ncvhs.hhs.gov/hipaa000706.pdf Viewed June 2004.; National Committee on Vital and Health Statistics, *Recommendations for PMRI Terminology Standards* (5 November 2003) (hereinafter PMRI Terminology Standards): http://www.ncvhs.hhs.gov/031105lt3.pdf Viewed June 2004.; *Key Capabilities of an Electronic Health Record System*, in IOM, n 26, at Executive Summary (hereinafter Executive Summary) and App E (hereinafter Key Capabilities of an Electronic Health Record System): http://www.nap.edu/books/0309090776/html/. Viewed June 2004. Viewed June 2004.
[77] Key Capabilities of an Electronic Health Record System, n 76 at 3.
[78] Executive Summary, n 76 at 8 (Recommendation 3).
[79] Consumers and doctors' offices are increasingly joining this infrastructure. For example, the The Federal Communications Commission has reported that broadband access from homes and businesses to the Internet increased by 20% during the second half of 2003, from 23.5 million to 28.2 million lines. For the 12-month period ending 31 December 2003, high-speed lines increased by 42%: FCC, *High-Speed Services for Internet Access: Status as of December 31, 2003*: http://www.fcc.gov/Bureaus/Common_Carrier/Reports/FCC-State_Link/IAD/hspd0604.pdf viewed June 2004.
[80] See eg Uniform Data Standards, n 76 at 19.
[81] See generally http://aspe.hhs.gov/admnsimp/index.shtml. Viewed June 2004. An example would be standards developed by ASC X12: http://www.x12.org/. Viewed June 2004.
[82] Pub L No 104-191, 110 Stat 1988. HIPAA-EDI transactions, such as health plan enrolment, eligibility, payment and remittance advice, claims, health plan premium payments, health claim status, and referral certification and authorisation, are dependent on messaging formats, transaction codes and data element codes that are conceptually related to those being developed for EHR systems.
[83] See generally Dolin RH et al, "The HL7 Clinical Document Architecture" (2001) 8 J Am Med Inform Assoc 552.
[84] See http://medical.nema.org/. Viewed June 2004.
[85] See http://www.ncpdp.org. Viewed June 2004.
[86] Uniform Data Standards, n 76 at 23-24.
[87] PMRI Terminology Standards, n 76.
[88] Key Capabilities of an Electronic Health Record System, n 76.
[89] See http://www.cdc.gov/nchs/about/otheract/icd9/abticd9.htm. Viewed June 2004.
[90] See http://www.ama-assn.org/ama/pub/category/3882.html. Viewed June 2004.
[91] See http://www.nlm.nih.gov/research/umls/rxnorm_main.html. Viewed June 2004.

adverse event or near-miss reporting)[92] and to adequately capture knowledge representation (such as clinical practice guidelines).

While the Health*Connect* architects apparently began with a picture of relatively limited data sets that patients could share, the United States architects are concentrating on the interoperability and comparability of *all* patient safety-related data,[93] designing a full "pull" architecture, with little apparent concept of what data consumers will extract from remote systems. In large part this seems to be a function of the United States timeline, with the IOM not expecting comprehensive EHR systems to be generally online until 2008-2010.[94] Currently, therefore, the United States work exists on a technical plain of functional models and data transparency and has not addressed the more normative questions surrounding who should have access to the data or who should make that decision. Of course, both NCVHS and the IOM are suitably sensitive to privacy and security issues and view them as critical components.[95] Notwithstanding, the nascent United States system appears to be driven by maximising patient safety data flow into local (decision-support) and national (safety-reporting) systems[96] and, at least in its present state of development, suggests patient autonomy will be marginalised.

Despite these real indications of coordinated progress in the United States, it is difficult to dispute Berwick's observation that "by a rational standard, we are making dreadful progress… Many, many lives could be saved … a lot of injuries could be prevented if we would move faster."[97]

COSTS, BARRIERS AND CONSEQUENCES

There is considerable uncertainty as to the costs associated with e-health initiatives. During transitional periods costs are likely to rise as both traditional and technologically mediated models work in parallel. It is also likely that improved access associated with technologically mediated care and a concomitant increase in treatment options will increase overall demand and hence spending. Most immediately, the health care industry will have to adjust to the costs associated with evolving technologies and increasingly short system lives. Equally, there are practical, political or professional barriers that impede the acceptance of EHR systems. For example, there are questions about whether records should be converted retrospectively or whether EHR systems should be prospective, and the medical community is concerned at ceding autonomy to technology companies.

Medical records (be they paper or electronic) do not exist in a legal vacuum. Most mature systems have ethical, legal and regulatory codes that govern the ownership of, access to and retention of records. These systems have also had to address issues relating to the quality of the record, particularly in regard to clinical negligence claims, and what may be thought of as the "evidentiary" bundle of rights and duties that generally describe the interface between records and legal processes (including the question of spoliation). Inevitably, these legal systems will have to be modified to reflect an EHR world. Equally, the legal system will have to come to terms with still more indeterminate costs, such as the interrelationship of EHR systems with privacy and litigation systems.

Privacy and confidentiality

Not surprisingly the EHR systems discussed herein fundamentally change the way patient data are acquired, stored, aggregated, processed, accessed and distributed. The systems must, therefore, confront privacy, confidentiality and security constraint models. In general terms, mature legal systems have chosen to protect patient data with either collection-centric or disclosure-centric models: the former restrict what data may be collected in what circumstances and by which actors; the

[92] For example, by using SNOMED CT http://www.snomed.org/snomedct/index.html. Viewed June 2004.
[93] See eg "Primary and Secondary Uses" in Key Capabilities of an Electronic Health Record System, n 76 at 5.
[94] Key Capabilities of an Electronic Health Record System, n 76 at 11.
[95] See eg Key Capabilities of an Electronic Health Record System, n 76 at 4.
[96] See generally Executive Summary, n 76. Therein the IOM notes (at 3): "As a result of the paucity of EHR systems, most patient safety reports cannot be generated automatically as a by-product of the patient care process. Nor can the lessons learned through analysis of patient safety reports easily be transferred back to the point of care."
[97] Dr DM Berwick, Institute for Health Care Improvement, quoted in Freudenheim , n 57, p C1.

latter is better described as a confidentiality system, typically regulating the *dissemination* and not the *collection* of data.[98]

In Europe,[99] the 1995 data directive suggested a mixed approach to protecting health data, providing that "personal data must be … collected for specified, explicit and legitimate purposes",[100] and also prohibiting the "processing of data concerning health".[101] The member states, however, have done little to promote a true collection-centric regime or meaningfully to limit the disclosure of patient information within the health care environment. For example, the *Data Protection Act 1998* (UK)[102] vests health information with the elevated protection classification of "sensitive personal data",[103] yet places few restrictions on data used in the context of the "provision of care and treatment and the management of health care services".[104]

In Australia,[105] the *Privacy Amendment (Private Sector) Act 2000* (Cth) extended the operation of the *Privacy Act 1988* (Cth) to cover the private sector, including health care,[106] and introduced the seminal National Privacy Principles.[107] The 1988 Act had established the position of Federal Privacy Commissioner,[108] and in 2001, the Commissioner issued *Guidelines on Privacy in the Private Health Sector*[109] that apply National Privacy Principles in the health context. The Guidelines provide for a robust collection-centric approach as, in most cases, they require consent prior to collecting patient health information, require disclosure of the purposes for which the information is being collected, and limit the data collected to "what is necessary for the health service provider's functions and activities".[110] The Guidelines distinguish between primary and secondary (such as commercial aggregation[111]) uses of patient data in terms of "the handling of information within an organisation" and "the transfer of information outside the organisation".[112] Crucially, the Guidelines state that a provider should "only use or disclose personal information for the primary purpose for which it was collected, or for directly related secondary purposes if these fall within the reasonable expectations of the individual".[113] Australian federal law has already been supplemented by State legislation, such as the *Health Records Information Privacy Act 2002* (NSW),[114] applying specifically to medical records.

In the United States[115] the *Health Insurance Portability and Accountability Act 1996* (US) committed the Federal Government to a process of "administrative simplification" to reduce health care costs. That mandate included regulatory authority to promulgate national *Standards for Privacy of Individually Identifiable Health Information*[116] (PIHI). These regulations place no limitations on

[98] Terry, n 24 at 225-227.
[99] Terry, n 24 at 227-228.
[100] Directive 95/46/EC of the European Parliament and of the Council of 24 October 1995 on the protection of individuals with regard to the processing of personal data and on the free movement of such data, Art 6(1)(b). See also Art 6(1)(c), providing for an additional proportionality test and Art 6(1)(e), essentially limiting the time data may be stored.
[101] Id., Art 8.1.
[102] See http://www.hmso.gov.uk/acts/acts1998/19980029.htm. Viewed June 2004.
[103] *Data Protection Act 1998* (UK), s 2.
[104] *Data Protection Act 1998* (UK), Schs 2, 3. For detailed information about the United Kingdom's progress on confidentiality for its EHR project see NHS Information Authority, *Consent and Confidentiality*: http://www.nhsia.nhs.uk/erdip/pages/evaluation/consentandconfid.asp. Viewed June 2004.
[105] Terry, n 24 at 229-230.
[106] Effective from 21 December 2001. For the consolidated legislation see http://www.privacy.gov.au/publications/privacy88_030504.pdf. Viewed June 2004.
[107] *Privacy Amendment (Private Sector) Act 2000* (Cth), Sch 3: http://www.privacy.gov.au/publications/npps01.html. Viewed June 2004.
[108] *Privacy Act 1988 (Cth)incorporating amendments made by the Privacy Amendment (Private Sector) Act 2000 (Cth)* s 27, "Functions of Commissioner".
[109] Office of the Federal Privacy Commissioner, *Guidelines on Privacy in the Private Health Sector* (October 2001): http://www.privacy.gov.au/publications/hg_01.html (hereinafter Guidelines). Viewed June 2004.
[110] Office of the Federal Privacy Commissioner, n 109 at 1.2.
[111] See eg *R v Department of Health; Ex parte Source Informatics Ltd* [2000] 2 WLR 940; *Re Pharmatrak, Inc Privacy Litigation* 292 F Supp 2d 263 (2003).
[112] Guidelines, n 109 at 2.
[113] Guidelines, n 109 at 2 "Use and Disclosure".
[114] See http://www.health.nsw.gov.au/csd/llsb/HealthRecordsPrivacy/HRIPAct.pdf. Viewed June 2004.
[115] Terry, n 24 at 228-229.
[116] 45 CFR Pts 160 and 164.

the collection of health data. It is a classic disclosure-centric system but, particularly after the Bush Administration removed any requirements of consent for data used for treatment purposes,[117] one that promises more than it delivers. Although the regulations limit use and disclosure with a "minimum necessary" rule,[118] that limitation is inapplicable in cases of treatment or when law requires the disclosure.[119] Further, PIHI permits disclosure to a very broad range of public health, law enforcement and judicial authorities[120] and less than robust consented-to disclosures for secondary uses.[121]

In summary, therefore, the European Union, at least in practice, has favoured a disclosure-centric approach. The United States has adopted a purely disclosure-centric approach to health privacy, albeit one backed by a comprehensive regulatory compliance model. In contrast, the Australian federal system mixes collection-centric and disclosure-centric principles. To a large extent the EHR systems that are emerging reflect the different approaches of these patient data regulatory systems. For example, Health*Connect* is heavily collection-centric and provides for considerable patient autonomy as to what data may be pushed to the centralised record summary. In contrast, the United States system, at least if it continues down its path to full horizontal interoperability, seems to contemplate no limitations on collection and, if the PIHI model is adopted, is unlikely to restrict the circulation of data among systems provided the data are being used for treatment purposes.

Litigation costs

Electronic health record systems, even those that adequately protect patient data, inevitably will incur costs because of their broader interactions with the legal system. Thus, it is likely that plaintiffs will attempt to leverage the new systems to promote their recovery in clinical negligence cases. For example, it is arguable that, initially at least, plaintiffs will derive litigation benefits from a secure, unalterable record.[122] A longitudinal record also will identify all provider-patient points of contact prior to an adverse event, thereby potentially increasing the pool of answerable defendants. Further, the availability of longitudinal patient data will inform the standard of care in clinical negligence cases, trapping health care providers who are late adopters of the technology. Similarly, aggressive plaintiffs' attorneys will attempt to use data-mining tools to identify related occurrences to bolster evidence or validate class actions, or even use their clients' rights of access and modification to manipulate the record.[123]

Equally, emerging EHR and linked systems, such as those used for decision-support, will themselves likely contain design and other operational flaws that will expose health care providers to legal risk. Early adopters are likely to face liability risks because of system deficiencies[124] or insufficient training, while those who wait for mature systems are likely to face actions for their failure to implement new but plaintiff-labelled "state-of-the-art" EHR systems.[125]

CONCLUSION

In general terms, the United States has made considerable progress towards implementing technologies that streamline health care transactions (including highly detailed security specifications[126]) and some progress towards the adoption of CPOE/CDSS systems. For the United

[117] §164.506.
[118] 45 CFR §164.502(b)(1).
[119] §164.502(b)(2).
[120] §164.512.
[121] §164.508.
[122] See generally Terry NP, "An eHealth Diptych: The Impact of Privacy Regulation on Medical Error and Malpractice Litigation" (2001) 27 Am J Law & Med 361.
[123] Terry, n 122.
[124] See eg Fernando B, Savelyich BSP, Avery AJ, Sheikh A, Bainbridge M, Horsfield P et al, "Prescribing Safety Features of General Practice Computer Systems: Evaluation Using Simulated Test Cases" (2004) 328 BMJ 1171 (noting flaws in prescribing systems used in the United Kingdom, particularly failure to warn where drug contraindicated).
[125] See generally Terry NP, "When the 'Machine That Goes "Ping"' Causes Harm: Default Torts Rules and Technologically-Mediated Health Care Injuries" (2002) 46 St Louis ULJ 37.
[126] See "Health Insurance Reform: Security Standards", 68 FR 8334: http://a257.g.akamaitech.net/7/257/2422/14mar20010800/edocket.access.gpo.gov/2003/03-3877.htm. Viewed June 2004.

States, therefore, the EHR is to some extent the "last piece of the puzzle" in creating a health information infrastructure. Australia, in very general terms, is in the opposite position, already testing aspects of its national EHR system but relatively undeveloped in its adoption of error-reducing or (and here because of far less need than in the United States) transactional technologies. The United Kingdom, apparently some way ahead of its European Union partners, recently embarked on an ambitious plan, seemingly on all fronts. Currently, the differences in progress that exist between these mature systems reveal less about the final nature of their EHR systems and more about process and their overall health care system models. In particular, and while hardly an original or nuanced observation, it is clear that the United Kingdom and Australian systems are centralised, "top-down" models, while changes in the United States tend to be more commercially-driven and "bottom-up".

The future of EHR systems is as clouded as any in the e-health domain. Will electronic records conquer the technical problems they pose, avoid the security and privacy costs their critics identify, and deliver lower costs and higher quality? Or will they be responsible for still more costs and errors, while promoting the continued industrialisation of health care delivery and subordinating patient autonomy and professional ideals to soulless systems? In addition to the technical challenges they pose to their architects, EHRs bring with them a complex array of challenges for health lawyers – challenges that must be addressed before these systems become fully operational. It has never been more important for health lawyers to be conversant with an emerging technology and to fully engage in its developmental processes so as to positively influence the EHRs' potential to improve care while preserving patient autonomy.

